

Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

**Summary of views and concerns expressed by deputations/individual
for the meeting on Tuesday, 20 May 2014**

Organization/individual	Major views and concerns
(a) Revised definition of "authorized seller of poisons"	
<ul style="list-style-type: none">• College of Primary Healthcare Pharmacists• Hong Kong Pharmacists Union• The Pharmaceutical Society of Hong Kong• The Practising Pharmacists Association of Hong Kong	<ul style="list-style-type: none">• The deputations were opposed to the proposed amendment under clause 4 of the Bill in respect of the definition of authorized seller of poisons ("ASP"). They considered that the meaning of the amended definition which defined ASP as "a registered pharmacist, body corporate or unincorporated body of persons that is authorized to carry on a business of retail sale of poisons under section 11" was unclear. In particular, The Practising Pharmacists Association of Hong Kong and Hong Kong Pharmacists Union were of the view that the proposed amendment was ambiguous about the respective legal liability of the owners of ASPs and those registered pharmacists who were employees of ASPs.• College of Primary Healthcare Pharmacists and Hong Kong Pharmacists Union suggested that the definition of ASP should remain as "a business authorized to sell poisons under section 11".
(b) Revised definition of "manufacture"	
<ul style="list-style-type: none">• School of Pharmacy, The Chinese University of Hong Kong	<ul style="list-style-type: none">• The deputation considered it necessary to ensure that the proposed amendment to the definition of "manufacture" under clause 4 of the Bill to cover expressly the packaging and repackaging activities of pharmaceutical products such that these activities should only be carried out by a licensed manufacturer who complied with the Good Manufacturing Practice ("GMP") requirement would not render ASPs not able to carry out, under the supervision of registered pharmacists, those repackaging activities for individual dispensing purpose.

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(c) Revised definition of "pharmaceutical product" and "medicine"	
<ul style="list-style-type: none"> • College of Consultant Pharmacist • College of Geriatric Pharmacy • Hong Kong Pharmacists Union • Chemical and Pharmaceutical Industries Council of the Federation of Hong Kong Industries • The Practising Pharmacists Association of Hong Kong • Primary Healthcare Quality Alliance 	<ul style="list-style-type: none"> • The deputations considered that the proposed amendment to the definition of pharmaceutical product and medicine under clause 4 of the Bill was ambiguous and not objective enough. They were concerned about the scope of products that would be regarded as "pharmaceutical product" by virtue of "presented as having properties for treating or preventing disease". There was a view from the Hong Kong Pharmacists Union that the definition of "pharmaceutical product" should remain as it was.
(d) To empower the Pharmacy and Poisons Board to issue codes of conduct and codes of practice for various licensed and listed traders, and registered pharmacists	
<ul style="list-style-type: none"> • Asia Regulatory Professional Association • Patients' Alliance on Healthcare Reform 	<ul style="list-style-type: none"> • The deputations supported the promulgation of codes of conduct ("COC") and codes of practice ("COP") for providing practical guideline in respect of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") for various types of licensed and listed traders, and registered pharmacists. Patients' Alliance on Healthcare Reform considered it appropriate for the Pharmacy and Poisons Board ("PPB"), which had widely consulted the relevant stakeholders on the revision or formulation of relevant COC or COP through the setting up of different working groups and the public consultation exercises, to issue the codes.
<ul style="list-style-type: none"> • Alliance of Safe and Quality Use of Medicines • College of Primary Healthcare Pharmacists 	<ul style="list-style-type: none"> • The deputations queried the appropriateness of empowering PPB under clause 6 of the Bill to promulgate COC and COP for various licensed and listed traders and registered pharmacists, and from time to time revise the whole or any part of the codes. In their view, the proposal would make the power of PPB too wide.

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<ul style="list-style-type: none"> • Drug Safety Consortium • Hong Kong Academy of Pharmacy • Hong Kong General Chamber of Pharmacy Limited • Hong Kong Pharmacists Union • The Pharmaceutical Society of Hong Kong • The Practising Pharmacists Association of Hong Kong • Primary Healthcare Quality Alliance 	<ul style="list-style-type: none"> • The deputations also expressed grave concern about the composition of PPB, particularly the lack of representation of pharmaceutical traders and registered pharmacists from various pharmaceutical professional bodies in PPB. Some deputations, including Alliance of Safe and Quality Use of Medicines, Hong Kong Academy of Pharmacy, Hong Kong Pharmacists Union and The Practising Pharmacists Association of Hong Kong called for a restructuring of PPB to ensure a balanced representation of members drawn from the trade. Drug Safety Consortium suggested that PPB should be restructured to become three boards each responsible for registration and control of pharmaceutical products; licensing and control of pharmaceutical traders; and registration and discipline of pharmacists. The Pharmaceutical Society of Hong Kong considered that the function of PPB should be confined to registration and control of pharmaceutical products, and licensing and control of pharmaceutical traders. • Given that the Bill was still under scrutiny, Hong Kong General Chamber of Pharmacy Limited expressed concern that PPB had already endorsed a new COP for ASP for taking effect on 2 January 2015. The deputation was particularly concerned about section 1.4 of the new COP which required that the key of the locked receptacles where all Part I poisons, antibiotics, psychotropic substances and dangerous drugs had to be kept by the registered pharmacist. In its view, this requirement did not conform to the existing regulation 19 of the Pharmacy and Poisons Regulations (Cap. 138A) ("the Regulations"). • Primary Healthcare Quality Alliance suggested that COC and COP should be developed from the bottom up, say, by representatives from pharmaceutical trade and pharmaceutical professional bodies respectively for endorsement by PPB.

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<ul style="list-style-type: none"> • Department of Pharmacology and Pharmacy, The University of Hong Kong • Hong Kong Doctors' Union • The Pharmaceutical Society of Hong Kong • School of Pharmacy, The Chinese University of Hong Kong • The Society of Hospital Pharmacists of Hong Kong 	<ul style="list-style-type: none"> • While agreeing the need to develop a COP for registered pharmacists, these deputations considered that the power to register pharmacists, promulgate a code of ethics or conduct and impose disciplinary sanctions against cases of misconduct should be vested with a separate statutory body, say, a pharmacy council, rather than PPB.
<ul style="list-style-type: none"> • Hong Kong Doctors' Union • Hong Kong Pharmaceutical Manufacturers Association 	<ul style="list-style-type: none"> • The deputations called for a review of the composition of PPB to include more representatives from the industry. There was a view from the Hong Kong Doctors' Union that it was not appropriate for the membership of PPB to continue to include a registered medical practitioner nominated by the Hong Kong Branch of the British Medical Association.
<ul style="list-style-type: none"> • Patients' Alliance on Healthcare Reform 	<ul style="list-style-type: none"> • The deputation considered that the proposal to establish a separate regulatory body from the current PPB for the registered pharmacists should be considered separately from the current legislative proposal.
(e) Qualification of authorized persons	
<ul style="list-style-type: none"> • Alliance of Safe and Quality Use of Medicines • College of Consultant Pharmacist • College of Geriatric Pharmacy • College of Primary Healthcare Pharmacists 	<ul style="list-style-type: none"> • On the introduction of an authorized persons system under clause 52 of the Bill, the deputations held a strong view that the requirement for registration as authorized person ("AP") under the proposed new regulation 30C of the Regulations should be confined to being a registered pharmacist in order to ensure the quality of pharmaceutical products. They considered that a person holding a qualification awarded on completion of a course recognized by the

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<ul style="list-style-type: none"> • Hong Kong Academy of Pharmacy • Hong Kong Doctors' Union • Hong Kong Pharmacists Union • Pharmaceutical Trade Alliance • The Practising Pharmacists Association of Hong Kong • Primary Healthcare Quality Alliance 	<p>Pharmacy and Poisons (Manufacturers Licensing) Committee and had three years or more relevant experience in manufacturing pharmaceutical products should not be regarded as competent to perform the duties of an AP set out under the proposed new regulation 30A(2). In their views, the proposal to allow these persons to register as APs ran contrary to the spirit of the Bill which was to, among others, enhance regulation of various aspects in the supply chain of pharmaceutical products.</p>
<ul style="list-style-type: none"> • Chemical and Pharmaceutical Industries Council of the Federation of Hong Kong Industries 	<ul style="list-style-type: none"> • The deputation queried the need to require registered pharmacist, who had undergo proper training, to have at least three years' relevant experience in manufacturing pharmaceutical products in order to be eligible to register as an AP.
<ul style="list-style-type: none"> • Department of Pharmacology and Pharmacy, The University of Hong Kong • The Hong Kong Association of the Pharmaceutical Industry • Patients' Alliance on Healthcare Reform • Ms Celine CHENG 	<ul style="list-style-type: none"> • The deputations were of the view that apart from registered pharmacists, persons holding recognized qualification and with relevant experience in manufacturing pharmaceutical products in accordance with the GMP Guide were also competent to act as APs.
(f) Extension of the maximum validity period of clinical trial certificate and medicinal test certificate	
<ul style="list-style-type: none"> • The Hong Kong Association of the Pharmaceutical Industry • Patients' Alliance on Healthcare Reform 	<ul style="list-style-type: none"> • The deputations supported the proposed amendment under clause 59 of the Bill to extend the validity of clinical trial certificate and medicinal test certificate to not more than five years. In their view, the current two-year validity was often too short for the completion of a clinical trial or medicinal test.

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<ul style="list-style-type: none"> • The Practising Pharmacists Association of Hong Kong • Primary Healthcare Quality Alliance 	<ul style="list-style-type: none"> • The deputation considered that the proposed extension of the maximum validity period of any clinical trial certificate or medicinal test certificate from two years to five years was too long. They urged the Administration to review the validity period.
(g) Labelling of pharmaceutical products	
<ul style="list-style-type: none"> • The Hong Kong Association of the Pharmaceutical Industry 	<ul style="list-style-type: none"> • The deputation supported the proposed amendments under clauses 21, 37 and 67 of the Bill to replace the text "Poison 毒藥", as required to be labeled on pharmaceutical products containing a poison, with "Prescription Drug 處方藥物" (for medicine containing a poison included in the Third Schedule of the Regulations) or "Drug under Supervised Sales 監督售賣藥物" (for medicine containing a poison included in Part I of the Poisons List but not containing a poison included in the Third Schedule of the Regulations).
<ul style="list-style-type: none"> • College of Consultant Pharmacist 	<ul style="list-style-type: none"> • The deputation agreed to the need to replace the term "Poison 毒藥", as required to be labeled on pharmaceutical products containing a poison, but considered it more appropriate to use "Prescription only medicine 處方藥品" instead of the proposed "Prescription drug 處方藥物", and "Pharmacist only medicine 藥劑師監售藥" instead of the proposed "Drug under Supervised Sales 監督售賣藥物".
(h) Recovery of conviction-related expenses	
<ul style="list-style-type: none"> • Hong Kong Pharmaceutical Manufacturers Association 	<ul style="list-style-type: none"> • The deputation was opposed to clause 30 of the Bill which provide for the recovery from any person convicted of an offence under the Ordinance of the costs and expenses incurred by the Government in collecting, analyzing or examining any poison, pharmaceutical product or other substance for the criminal proceedings, as such penalty was not required in other criminal cases.

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	The Administration should instead consider imposing heavier penalties to increase deterrent effect.
(i) Chinese text of the term "expiry date"	
<ul style="list-style-type: none"> Chemical and Pharmaceutical Industries Council of the Federation of Hong Kong Industries 	<ul style="list-style-type: none"> The deputation suggested to replace "使用期限" with "有效期限" or "失效期限" in the Chinese text of the term "expiry date" under clause 53 of the Bill which, in its view, would be more accurate in the literal meaning of the term and in line with the Chinese text used in other legislation.
(j) Placing drug orders in written form	
<ul style="list-style-type: none"> The Hong Kong Association of the Pharmaceutical Industry Patients' Alliance on Healthcare Reform 	<ul style="list-style-type: none"> The deputations supported the proposed requirement that all orders for pharmaceutical products to be have written records, as the proposal could help to maintain a complete set of movement records of pharmaceutical products and minimize errors in delivery of pharmaceutical products for the sake of patient safety.
<ul style="list-style-type: none"> Hong Kong Alliance for Patients' Organizations Hong Kong Doctors' Union 	<ul style="list-style-type: none"> The deputations were opposed to the proposed requirement of placing orders of pharmaceutical products in written form, as it might result in possibility of delay in the ordering of pharmaceutical products. In their views, the Administration was trying to circumvent the scrutiny of the Legislative Council on the proposed requirement by implementing it through administrative means. There was a view from The Hong Kong Alliance for Patients' Organizations that the Administration should promote the use of electronic drug ordering system.

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(k) Requiring registered pharmacist employed by an ASP be present whenever the ASP is opened for business	
<ul style="list-style-type: none"> • Department of Pharmacology and Pharmacy, The University of Hong Kong • School of Pharmacy, The Chinese University of Hong Kong 	<ul style="list-style-type: none"> • The deputation requested the Administration to re-consider introducing the proposed requirement in the Bill, so as to ensure that ASPs would be under the personal control of registered pharmacists for the provision of safe and professional pharmaceutical service to the general public.
(l) Establishment of pharmacovigilance monitoring platform	
<ul style="list-style-type: none"> • Department of Pharmacology and Pharmacy, The University of Hong Kong • School of Pharmacy, The Chinese University of Hong Kong • The Society of Hospital Pharmacists of Hong Kong 	<ul style="list-style-type: none"> • The deputations considered that the Bill should provide for mandatory reporting of adverse drug events so as to avoid future incidents of undesirable drug-related outcomes.
(m) Roles of pharmacists	
<ul style="list-style-type: none"> • Department of Pharmacology and Pharmacy, The University of Hong Kong • School of Pharmacy, The Chinese University of Hong Kong • The Society of Hospital Pharmacists of Hong Kong 	<ul style="list-style-type: none"> • The deputations considered that primary care should be included as part of the duties of pharmacists.

<u>Organization/individual</u>	<u>Submission [LC Paper No.]</u>
Asia Regulatory Professional Association	LC Paper No. CB(2)1522/13-14(03) LC Paper No. CB(2)1649/13-14(02)
Chemical and Pharmaceutical Industries Council of the Federation of Hong Kong Industries	LC Paper No. CB(2)1584/13-14(06)
Department of Pharmacology and Pharmacy, The University of Hong Kong	LC Paper No. CB(2)1584/13-14(05) LC Paper No. CB(2)1743/13-14(01)
Hong Kong Alliance of Patients' Organizations	LC Paper No. CB(2)1649/13-14(03)
The Hong Kong Association of the Pharmaceutical Industry	LC Paper No. CB(2)1743/13-14(01)
Hong Kong Doctors Union	LC Paper No. CB(2)1560/13-14(01)
Hong Kong General Chamber of Pharmacy Limited	LC Paper No. CB(2)1522/13-14(02)
Patients' Alliance on Healthcare Reform	LC Paper No. CB(2)1694/13-14(01)
Hong Kong Pharmaceutical Manufacturers Association	LC Paper No. CB(2)1649/13-14(01)
The Pharmaceutical Society of Hong Kong	LC Paper No. CB(2)1522/13-14(04) LC Paper No. CB(2)1743/13-14(01)
Primary Healthcare Quality Alliance	LC Paper No. CB(2)1584/13-14(07)
The Society of Hospital Pharmacists of Hong Kong	LC Paper No. CB(2)1584/13-14(05) LC Paper No. CB(2)1743/13-14(01)
School of Pharmacy, The Chinese University of Hong Kong	LC Paper No. CB(2)1584/13-14(05) LC Paper No. CB(2)1678/13-14(01) LC Paper No. CB(2)1743/13-14(01)
The Society of Hospital Pharmacists of Hong Kong	LC Paper No. CB(2)1584/13-14(05)
Ms Celine CHENG	LC Paper No. CB(2)1743/13-14(02)